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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Max Cynader et al.
Application No. : 09/301,507
Filed : April 28, 1999
For : GENE SEQUENCES ASSOCIATED WITH NEURAL PLASTICITY AND METHODS RELATED THERETO
Examiner : James Martinell, Ph.D.
Art Unit : 1631
Docket No. : Not yet assigned (230018.401C1)
Date : October 4, 2002

Box AF
Commissioner for Patents
Washington, DC 20231

RESPONSE TO OFFICE ACTION

Commissioner for Patents:

Applicants submit this response to the Office Action dated June 4, 2002, and also in response to the Office communication dated July 1, 2002, which contained a summary of the telephone interview held on July 10, 2002. Applicants thank the Examiner for the courtesy and assistance during the telephone interview.

Claims 57-62 are pending in the application. SEQ ID NO:74 has been elected and is under examination. Claims 57-62 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one of skill in the art to make and/or use the invention. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner provided five grounds to support the rejection, and these are addressed individually. First, the Examiner stated that neither Berger et al. (Acta Anat. 162:95, 1998) nor Chen et al. (Nat. Genet. 1:204, 1992) was of record. A copy of Berger et al. is

submitted herewith. During the telephone interview, the Examiner acknowledged that Chen et al. is of record. (See Paper No. 10 at page 4, last paragraph, and accompanying PTO-892 form.)

Second, the Examiner stated that Berger et al. was published after the effective filing date of this application. Although that is the case, Berger et al. is cited to support the conclusion that the present application discloses the importance of mutations in the proteins of the application, particularly, for the present claims, SEQ ID NO:74. The role of mutations is discussed further in the context of point 4, below.

Third, the Examiner states that there is no alignment of SEQ ID NO:74 and the Norrie gene in the record. Applicants respectfully note that an alignment was filed on March 18, 2002 as Exhibit 1. A copy is attached for the Examiner's reference.

Fourth, the Examiner states that applicants have not indicated which parts of the application teach how to use SEQ ID NO:74 or what the meaning of results from an assay might be. In the Interview Summary, the Examiner kindly stated that he would consider arguments related to utilities such as screening and gene therapy. The Examiner's attention is first drawn to the paragraph bridging pages 28 and 29, which discusses the relationship between genes and diseases mapped to a particular chromosomal region associated with a gene. At lines 6-11 on page 29, the specification states the following:

If a mutation is observed in some or all of the affected individuals but not in any normal individuals, then the mutation is likely to be the causative agent of the disease.

Thus, detection of a mutation of the gene associated with SEQ ID NO:74 is clearly contemplated in the application, and the fact that Berger et al. have noted an association between mutations of the Norrie gene (which corresponds to SEQ ID NO:74) basically supports applicants' original statements regarding the role of the identified sequences in disease. Detection of such mutations using SEQ ID NO:74 is a specific, substantial and real-world utility of the claimed sequences.

Another utility disclosed in the application is gene therapy. Applicants respectfully direct the Examiner's attention to the specification beginning at page 34, line 22, which discloses the delivery of the polynucleotides of the invention (in this case, SEQ ID NO:74) to the particular neuronal tissue in need. The gene would provide neural plasticity at that location, thus remedying a defect in the individual needing treatment. Methods for carrying out the gene therapy are discussed in detail at page 34, line 27, through page 40, line 26.

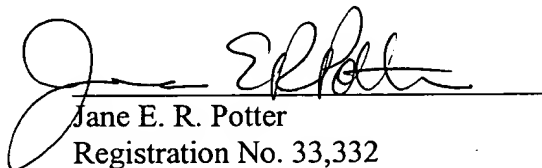
Applicants submit that the specification clearly supports utilities of the disclosed sequence as a screening tool and as an agent of gene therapy, thus enabling one of skill in the art to make and use the invention.

Finally, the Examiner notes that the application states that SEQ ID NO:1-93 did not demonstrate identity with known amino acid sequences. Applicants request that the Examiner view the specification in the context of the filing date, at which time there was a strong focus on the novelty of DNA sequences, and the guidelines relating to utility and enablement had not been fully articulated by the Patent Office or by the Courts. Applicants in good faith submitted the application in the context of the existing guidelines. Were the same application to be filed today, the information regarding the homology with the Norrie gene could have been incorporated into the disclosure, instead of being submitted during prosecution as part of the record. However, the changing standards under which these applications are examined should not preclude an applicant from being entitled to claim his or her discovery. In this case, the discovery is that a gene homologous to the human Norrie gene plays a role in brain plasticity in cats, and thereby provides methods and tools for screening and treatment of disease states related to abnormalities or mutations in the gene.

For the foregoing reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

Claims 57-62 are rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility, for reasons of record (Office Action mailed September 18, 2001, page 4). Applicants submit that the remarks above are applicable to the rejection under this paragraph, and respectfully submit that the claimed invention does have patentable utility as described in detail above.

Respectfully submitted,



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